Section 5. 510(k) Summary

K Number K140131

APR 0 3 2014

Submission Date: January 14, 2014

General Information

Classification	Class II
Trade Name	SUB-Q Subcutaneous Tissue Infusion Set
Common Name:	I.V. Administration Set
Classification Name and Reference:	Intravascular Administration Set 21 CFR §880.5440
Product Code and Class	FPA, Class II
Predicate Device	Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)
Submitter	Peter Kollings EMED Technologies Corporation 1264 Hawks Flight Ct., Ste. 200 El Dorado Hills, Ca 95762 Tel: 916.932.0071 x114 Fax: 916.932.0074

Purpose of Submission

This submission is intended to provide notification of modifications to our current legally marketed SUB-Q Subcutaneous Tissue Infusion Set device cleared under K020530. These modifications are the result of variations to the original device, resulting in a selection of infusion sets intended to satisfy individual user needs. Label changes are to reflect current corporate identity of the SUB-Q Subcutaneous Tissue Infusion Set.

Device Description

The EMED SUB-Q Subcutaneous Tissue Infusion Set (SUB-Q Set) device consists of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place. Each infusion set has a luer lock at one end and a 90 degree 24g or 27g needle

mounted to a standard or closing wing-stabilizer at the distal end of one or more lumens. Each lumen is connected by lengths of tubing and a number connectors, depending on configuration. The luer lock is used to connect to the infusion source. The needles are treated with medical grade silicone for ease of insertion into the skin. The device is for single use.

Intended Use

The SUB-Q Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

This is the same intended use as previously cleared for the Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530).

Technological Characteristics

The EMED SUB-Q Set has the same intended use as previously cleared for the predicate device (K020530).

The EMED SUB-Q Set incorporates the core design, same operating principle, and same materials as the predicate product (see K020530).

The EMED SUB-Q Set is assembled at the same facility as the predicate, under the same manufacturing processes as the predicate, and are tested against the same performance and batch release criteria as the predicate.

The EMED SUB-Q Set is packaged in the same manner using the same packaging materials and process as the predicate product (see K020530).

The EMED SUB-Q Sets are be sterilized to a sterility assurance level (SAL) of 10^{-6} using the same validated process as the predicate, and have the same specified storage conditions and 5 year shelf-life as the predicate (see K020530).

The EMED SUB-Q Set contains the following modifications to the predicate device (K020530):

- Various numbers of lumens were made available as configuration options.
- PVC bi-furcator and tri-furcator tubing connectors were added to the design to create from 2 to 6 lumens.
- 24g needle was made an available configuration option, with a corresponding change to tubing diameter.
- Needles received application of medical grade silicone lubricant to aid in insertion and increase patient comfort and satisfaction.
- Various needle lengths were made available configuration options
- Various tubing length variations were made available as configuration options.

- A proprietary wing closure mechanism was made an available configuration option to aid in handling and disposal.
- Open end slide clamps to stop flow.
- Labeling updated to reflect the additional available configurations and current corporate identity (new ownership, logos, address, etc.).

The fundamental scientific technology, indications for use, materials, design, sterilization and packaging are not impacted by these changes, and remain identical between the proposed and predicate devices.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED SUB-Q Set and the predicate (K020530).

Table 5-1

	EMED SUB-Q Subcutaneous Tissue Infusion Set	**Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)**
Indications for Use	Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The device is supplied sterile, for singly use only. It is a prescription device.	Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The device is supplied sterile, for singly use only. It is a prescription device.
Material/ Components	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC (std) and Polyproylene (locking) Connectors: PVC Needles: Stainless Steel Slide Clamp: ABS Bonding Agent: Loctite 3341	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC Connectors: None Needles: Stainless Steel Slide Clamp: None Bonding Agent: Loctite 3341
Device Length	Ranging from 2" - 36" (based on configuration)	42"
Tubing ID	0.200" (27g)	0.200" (27g)

	EMED SUB-Q Subcutaneous Tissue Infusion Set	**Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)**
	0.260 (24g)	
Needle gage	24 gage and 27 gage	27 gage
Needle Lengths	Ranging from 6 mm - 16 mm (based on configuration)	6 mm
Number of Lumens	1 - 6	1
Wing type	Standard and Closing	Standard
Clamp Type	Slide	None
Needle Lubricant	Dow Corning 360 polydimethylsiloxane	None

Device Performance

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Non-clinical testing of the EMED SUB-Q Set included leakage, occlusion, and joint-strength which demonstrated the device meets the requirements for its intended use. The testing also demonstrates that the EMED SUB-Q Set meets performance criteria and is substantially equivalent to the predicate device as related to device performance.

Summary of Substantial Equivalence

The EMED Technologies Corporation SUB-Q Subcutaneous Tissue Infusion sets have the same basic design, fundamental scientific technology, indications for use, materials, sterilization, and packaging as the predicate, and therefore are substantially equivalent to the commercially available predicate device. Any differences between the EMED SUB-Q Subcutaneous Tissue Infusion Set and the predicate do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

EMED Technologies Corporation
C/O Peter Kollings
Director Regulatory Affairs and Quality Assurance
1264 Hawks Flight Court, Suite 200
El Dorado Hills, CA 95762

Re: K140131
Trade/Device Name: SUB-Q Subcutaneous Tissue Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 10, 2014
Received: March 12, 2014

Dear Mr. Kollings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140131

Device Name
SUB-Q Subcutaneous Tissue Infuset Set

Indications for Use *(Describe)*
SUB-Q Subcutaneous Tissue Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA
Digitally signed by
Richard C. Chapman
Date: 2014.04.03
10:58:53 -04'00'

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